

Remarks

The Office Action mailed June 19, 2000, has been received and reviewed. Claims 1 through 12 and 14 through 21 are currently pending in the application, and each of claims 1 through 12 and 14 through 21 stand rejected. In addition, claims 3, 6, 9, 10, 17 and 20 are objected to due to informalities. The application is to be amended as previously set forth. All amendments are made without prejudice or disclaimer. Reconsideration is respectfully requested.

1. Priority Claim

Applicants' representative has requested a certified copy of EP 97201440.1, and will forward it to the Office upon receipt.

2. Claim Objections

Claims 3, 6, 9, 10, 17, and 20 are objected to due to informalities. Specifically, each such claim is objected to the British spelling of the word "hybridize". (*See, Office Action*, page 2). Applicants respectfully note that the objection has been overcome by the amendments previously set forth herein. Therefore, applicants respectfully request that the objection to claims 3, 6, 9, 10, 17, and 20 be withdrawn.

3. 35 U.S.C. § 112 , Second Paragraph, Rejections

Claim 10 stands rejected under 35 U.S.C. § 112, second paragraph (hereinafter "Section 112, second paragraph"), as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. In particular, the Office Action asserted that "[c]laim 10 is indefinite for 'under low-stringent conditions' because the hybridization conditions have not been defined" (*Office Action*, page 3). Applicants have amended the claim to remove the terminology, and thus request that the rejection of claim 10 be withdrawn.

Claims 11, 12, 14, and 15 also stand rejected under Section 112, second paragraph, as assertedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. Specifically, it was asserted that claims 11, 12, 14, and 15 were "incomplete for omitting essential steps. . . ." (*Id.*). Applicants have amended these claims, and, in view of the amendments, respectfully request that the rejection be withdrawn.

4. 35 U.S.C. § 112/101 Rejections

Claim 11 was rejected under 35 U.S.C. § 112/101. It was asserted that "the claim does not set forth any steps involved in the method/process" (*Id.*) It is further asserted that, "because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process . . .," claim 11 is not proper under 35 U.S.C. § 101. (*Id.*) However, as already noted, applicants have amended claim 11, and applicants respectfully submit that claim 11, as amended, recites positive method steps describing how the method recited therein is carried out. Therefore, applicants respectfully request that these rejections be withdrawn.

5. 35 U.S.C. § 102(b) Rejections

Claims 1 through 12 and 14 through 21 are rejected in the Office Action under 35 U.S.C. § 102(b) ("Section 102(b)"), as assertedly being anticipated by either U.S. Patent 5,487,970 ("Rowley") or by an article entitled, "Detection of *bcr-abl* Fusion in Chronic Myelogenous Leukemia by in Situ Hybridization," authored by D.C. Tkachuk et al. ("Tkachuk et al."). However, a claim is anticipated under Section 102(b) only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Brothers v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). As is detailed hereafter, neither of the references cited in the Office Action explicitly or inherently teach each of the limitations of any one of the claims pending in the instant application, particularly in light of the amendments included herein. Applicants therefore, respectfully traverse the rejections of claims 1 through 12 and 14 through 21 and respectfully request that such rejections be withdrawn.

Rejection of Claims 1 through 12, 14, 15, and 17 through 21

Claims 1 through 12, 14, 15, and 17 through 21 are rejected in the Office Action as anticipated by Tkachuk et al. under Section 102(b). However, applicants respectfully submit that Tkachuk et al. does not explicitly or inherently teach each of the limitations included in any one of the rejected claims. Claims 1 through 10 and 17 through 21, as amended, each recite a pair of distinct, comparably sized nucleic acid probes which flank a potential breakpoint in a chromosome, and claims 12, 14, and 15 recite methods that require the provision of such probes. In contrast,

Tkachuk et al. teaches the use of a pair of nucleic acid probes which are dissimilar in size (the c-H-*abl* probe being nearly double the size of the PEM12 probe), and, instead of flanking a potential breakpoint in a chromosome, one of the probes of the probe pair taught in Tkachuk et al., the PEM12 probe, overlaps the targeted potential breakpoint. As a consequence, Tkachuk et al. does not expressly or inherently teach each of the limitations recited in any one of claims 1 through 12, 14, 15, or 17 through 21, and applicants, therefore, respectfully request that the rejection of claims 1 through 12, 14, 15, and 17 through 21 under Section 102(b) be withdrawn.

Rejection of Claim 16

Claim 16 was rejected in the Office Action under Section 102(b), as assertedly being anticipated by Rowley et al. However, applicants respectfully submit that Rowley et al. does not explicitly or inherently teach each of the limitations included in any one of the rejected claims. Claim 16 recites a diagnostic kit comprising "at least the nucleic acid probes of claim 1," and the nucleic acid probes of claim 1 comprise:

[a] pair of distinct nucleic acid probes having comparable size, said size being selected from the group consisting of from 1 to 100 kb, 1 to 10 kb, 7 to 15 kb, 10 to 20 kb, 10 to 30 kb, 20 to 40 kb, 30 to 50 kb, 40 to 60 kb, 50 to 70 kb, 60 to 80 kb, 70 to 90 kb and 80 to 100 kb, and flanking a potential breakpoint in a chromosome, each of said pair of distinct probes being labeled with at least one different reporter molecule.

In contrast, the diagnostic kits taught in Rowley et al. do not include pairs of distinct, comparably sized probes as recited in claim 1.

Rowley et al. teaches kits that may include one or more probes. Further, Rowley et al. teaches that the sequence of the one or more probes may be chosen from four different nucleic acid sequences. However, Rowley et al. simply does not teach kits comprising a pair of distinct nucleic acid probes of comparable size and flanking a potential breakpoint in a chromosome. Therefore, Rowley et al. does not expressly or inherently teach each of the limitations recited in claim 16, and applicants respectfully request that the rejection of claim 16 under Section 102(b) be withdrawn.

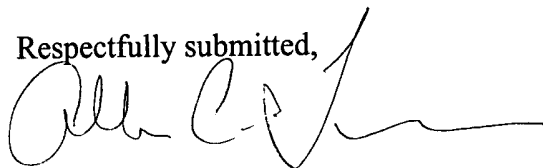
6. Other Prior Art

Receipt of the Russo et al. reference is acknowledged. No further comment from the applicants is believed necessary.

Conclusion

Claims 1 through 12 and 14 through 21 are believed to be in condition for allowance, and an early notice thereof is respectfully solicited. Should the Office determine that additional issues remain which might be resolved by a telephone conference, the Examiner is respectfully invited to contact applicants' undersigned attorney.

Respectfully submitted,



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